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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                | CONFIRMATION NO.       |
|--|-------------|----------------------|------------------------------------|------------------------|
| 09/914,176   | 06/06/2005  | Gary Lawrence French | IMA-031.01                         | 1966                   |
| 25181  | 7590        | 01/24/2008           |                                    |                        |
| FOLEY HOAG, LLP<br>PATENT GROUP, WORLD TRADE CENTER WEST<br>155 SEAPORT BLVD<br>BOSTON, MA 02110 |             |                      | EXAMINER<br>BERTAGNA, ANGELA MARIE |                        |
|  |             |                      | ART UNIT<br>1637                   | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>01/24/2008            | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|  |                                      |  |                                      |  |
|--|--------------------------------------|--|--------------------------------------|--|
| <p align="center"><b>Office Action Summary</b></p> | <b>Application No.</b><br>09/914,176 |  | <b>Applicant(s)</b><br>FRENCH ET AL. |  |
|  | <b>Examiner</b><br>Angela Bertagna   |  | <b>Art Unit</b><br>1637              |  |
|  |                                      |  |                                      |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-50, 62-65 and 78-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 39-50, 62-65, 78-85 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Application***

1. Applicant's response filed November 5, 2007 is acknowledged. Claims 39-50, 62-65, and 78-85 are currently pending. Applicant's election of Group II in the response filed on April 23, 2007 is also acknowledged. The addition of new claims 78-85 has necessitated this supplemental lack of unity requirement. Also, upon further consideration, the lack of unity requirement made previously between the methods of claims 39-50 and the kits of claims 62-65 and 78-85 is withdrawn. An election of species requirement follows below.

### ***Election/Restrictions***

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Each different oligonucleotide of SEQ ID NO: 3-63 constitutes a different species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an

allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species 1 (SEQ ID NO: 3) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 2 (SEQ ID NO: 4) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 3 (SEQ ID NO: 5) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 4 (SEQ ID NO: 6) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 5 (SEQ ID NO: 7) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 6 (SEQ ID NO: 8) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 7 (SEQ ID NO: 9) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 8 (SEQ ID NO: 10) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 9 (SEQ ID NO: 11) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 10 (SEQ ID NO: 12) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 11 (SEQ ID NO: 13) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 12 (SEQ ID NO: 14) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 13 (SEQ ID NO: 15) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 14 (SEQ ID NO: 16) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 15 (SEQ ID NO: 17) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 16 (SEQ ID NO: 18) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 17 (SEQ ID NO: 19) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 18 (SEQ ID NO: 20) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 83, 84, and 85  
Species 19 (SEQ ID NO: 21) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 20 (SEQ ID NO: 22) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 21 (SEQ ID NO: 23) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 22 (SEQ ID NO: 24) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 23 (SEQ ID NO: 25) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 24 (SEQ ID NO: 26) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 25 (SEQ ID NO: 27) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 26 (SEQ ID NO: 28) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 27 (SEQ ID NO: 29) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 28 (SEQ ID NO: 30) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 29 (SEQ ID NO: 31) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 30 (SEQ ID NO: 32) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 83, 84, and 85  
Species 31 (SEQ ID NO: 33) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 32 (SEQ ID NO: 34) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 33 (SEQ ID NO: 35) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 34 (SEQ ID NO: 36) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 35 (SEQ ID NO: 37) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 36 (SEQ ID NO: 38) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 37 (SEQ ID NO: 39) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 38 (SEQ ID NO: 40) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 39 (SEQ ID NO: 41) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85

Species 40 (SEQ ID NO: 42) – claims 39-43, 46, 45, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 41 (SEQ ID NO: 43) – claims 39-43, 46, 45, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 42 (SEQ ID NO: 44) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 43 (SEQ ID NO: 45) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 44 (SEQ ID NO: 46) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 45 (SEQ ID NO: 47) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 46 (SEQ ID NO: 48) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 47 (SEQ ID NO: 49) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 48 (SEQ ID NO: 50) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 50 (SEQ ID NO: 51) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 51 (SEQ ID NO: 52) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 52 (SEQ ID NO: 53) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 53 (SEQ ID NO: 54) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 54 (SEQ ID NO: 55) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 55 (SEQ ID NO: 56) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 56 (SEQ ID NO: 57) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 57 (SEQ ID NO: 58) – claims 39-44, 46, 48-50, 62-65, 78, 79, 81, 84, and 85  
Species 58 (SEQ ID NO: 59) – claims 39-43, 45, 46, 48-50, 62-65, 78, 80, 81, 84, and 85  
Species 59 (SEQ ID NO: 60) – claims 39-43, 47-50, 62-65, 78, 82, 84, and 85  
Species 60 (SEQ ID NO: 61) – claims 39-43, 47-50, 62-65, 78, 82, 84, and 85  
Species 61 (SEQ ID NO: 62) – claims 39-43, 47-50, 62-65, 78, 82, 84, and 85  
Species 62 (SEQ ID NO: 63) – claims 39-43, 47-50, 62-65, 78, 82, 84, and 85

The following claim(s) are generic: claims 39 and 62.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above oligonucleotides has a different nucleotide sequence and functions to identify a different portion of a bacterial 23S rDNA sequence from different microorganisms (see pages 5-10 of the specification). As a result, the claimed oligonucleotides (SEQ ID NO: 3-63) do not share a same or corresponding special technical feature, and an election of species requirement is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMB

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/Cynthia Wilder/  
Patent Examiner  
Art Unit 1637